



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Zoetis Inc.
USDA Vet Biologics Establishment Number	190
Product Code	2691.01
True Name	Leptospira Pomona Bacterin
Tradenname(s) / Distributor or Subsidiary (if different from manufacturer)	Lepto EQ Innovator - No distributor specified
Date of Compilation Summary	December 16, 2019

Disclaimer: Do not use the following studies to compare one product to another. Slight differences in study design and execution can render the comparisons meaningless.

Study Type	Efficacy																					
Pertaining to	<i>Leptospira interrogans</i> serovar <i>pomona</i> (<i>L. pomona</i>)																					
Study Purpose	Demonstrate efficacy against <i>L. pomona</i> infection in horses.																					
Product Administration	Two doses, administered intramuscularly, 3 weeks apart.																					
Study Animals	30 horses, approx. 6 months of age, randomly divided into 15 controls and 15 vaccinates.																					
Challenge Description	Three weeks following the second vaccination, all animals were challenged with <i>L. pomona</i> for 3 consecutive days (Study Day 42, 43, and 44).																					
Interval observed after challenge	Animals were observed daily for any clinical signs of leptospirosis for 28 days post-challenge (Day 1 post-challenge is Study Day 43). Local and systemic reactions were observed for 2 hours post-vaccination. Urine samples were evaluated post-challenge. Liver and kidney tissues were examined at 28 days post-challenge (Study Day 70).																					
Results	<p><u>Urine, kidney, and liver samples from each animal were analyzed for the presence of <i>L. pomona</i>.</u></p> <p><u>Table 1: Number of horses with Reisolation of <i>L. pomona</i></u></p> <table border="1"> <thead> <tr> <th rowspan="2">Treatment Group</th> <th colspan="3">Isolation from samples: Number/Total (%)</th> </tr> <tr> <th>Urine</th> <th>Kidney</th> <th>Liver</th> </tr> </thead> <tbody> <tr> <td>Control (T01)</td> <td>14/15 (93.3%)</td> <td>3/15 (20%)</td> <td>0/15 (0%)</td> </tr> <tr> <td>Vaccinate (T02)</td> <td>0/15 (0%)</td> <td>0/15 (0%)</td> <td>0/15 (0%)</td> </tr> </tbody> </table> <p><u>Table 2: Number of horses with Fever (>103.0°F) Post-Challenge</u></p> <table border="1"> <thead> <tr> <th>Treatment Group</th> <th>Number/Total (%)</th> </tr> </thead> <tbody> <tr> <td>Control (T01)</td> <td>10/15 (66.7%)</td> </tr> <tr> <td>Vaccinate (T02)</td> <td>3/15 (20%)</td> </tr> </tbody> </table> <p>There were no other clinical signs of icterus, ocular discharge, dehydration, oliguria, or conjunctivitis present in either group following the challenge.</p>	Treatment Group	Isolation from samples: Number/Total (%)			Urine	Kidney	Liver	Control (T01)	14/15 (93.3%)	3/15 (20%)	0/15 (0%)	Vaccinate (T02)	0/15 (0%)	0/15 (0%)	0/15 (0%)	Treatment Group	Number/Total (%)	Control (T01)	10/15 (66.7%)	Vaccinate (T02)	3/15 (20%)
Treatment Group	Isolation from samples: Number/Total (%)																					
	Urine	Kidney	Liver																			
Control (T01)	14/15 (93.3%)	3/15 (20%)	0/15 (0%)																			
Vaccinate (T02)	0/15 (0%)	0/15 (0%)	0/15 (0%)																			
Treatment Group	Number/Total (%)																					
Control (T01)	10/15 (66.7%)																					
Vaccinate (T02)	3/15 (20%)																					
USDA Approval Date	14 January 2014																					

Table 3: Individual Animal Temperature Data

Assigned Number	Group	Study Day														
		40	41	(DOC) 42	(DOC) 43	(DOC) 44	45	46	47	48	49	50	51	52	53	54
802	1	102.1	101.9	101.7	102.5	102.8	102.8	101.7	101.8	101.8	102.2	102.3	102.3	102.2	102.4	102.1
807	1	101.6	101.5	102.2	101.7	102.5	102.6	102.5	101.8	101.8	101.5	101.7	101.7	101.9	102.4	101.6
809	1	101.2	101.6	101.0	101.6	101.9	103.6	103.0	101.2	101.6	101.2	101.1	101.3	101.8	101.3	101.4
810	1	101.1	101.4	101.9	101.6	101.8	102.0	102.0	101.5	101.4	101.1	101.5	101.3	101.4	101.7	101.3
811	1	101.3	102.1	101.6	101.5	102.5	102.9	103.3	102.1	102.0	102.2	101.5	101.6	101.9	102.3	102.3
813	1	101.3	101.8	101.5	101.7	103.4	103.5	102.7	101.3	101.6	101.9	101.6	101.3	101.6	101.8	101.5
814	1	101.1	101.7	101.8	102.2	103.1	103.2	102.0	101.8	101.8	102.0	101.9	101.5	101.8	101.6	101.6
816	1	101.5	101.7	101.2	101.7	104.0	103.8	101.5	101.2	101.5	101.9	102.0	101.9	101.1	102.0	101.9
819	1	101.8	101.2	101.6	101.7	101.6	101.8	102.4	101.2	101.2	101.3	101.0	101.5	101.5	101.5	101.0
820	1	102.3	101.6	102.0	101.6	102.1	102.2	103.8	102.6	102.2	101.6	101.5	101.6	101.7	101.9	101.8
821	1	101.6	102.2	101.9	101.7	103.0	103.5	102.1	101.5	101.7	102.1	101.8	101.8	102.2	101.7	102.1
822	1	101.7	101.6	101.1	101.5	102.4	102.2	103.2	101.0	101.4	100.8	101.0	101.4	101.6	101.9	101.0
825	1	101.0	101.4	101.8	101.4	103.0	103.0	102.1	101.7	101.5	101.2	101.5	101.0	101.4	101.7	101.5
827	1	101.8	102.5	102.4	102.4	102.4	102.6	102.0	101.4	101.7	102.0	102.4	101.8	102.3	101.8	101.8
828	1	101.4	101.6	101.1	102.0	105.3	106.0	104.0	101.6	100.8	100.8	100.8	100.9	101.9	101.1	101.0
801	2	101.7	102.3	101.7	102.4	101.6	102.0	101.6	101.5	101.5	101.4	101.8	101.7	101.3	102.0	102.0
803	2	101.6	101.8	101.4	102.4	102.6	101.9	101.5	101.0	101.4	101.4	101.8	101.1	101.7	101.4	101.8
804	2	102.0	101.8	101.5	102.3	102.4	102.8	101.9	101.9	102.1	101.6	101.4	101.6	101.7	101.7	102.0
805	2	101.4	101.6	101.4	102.3	102.7	102.2	101.2	100.8	101.8	101.8	101.7	101.6	101.8	101.6	101.6
806	2	100.8	100.9	101.7	101.0	101.5	102.3	101.0	101.3	100.8	100.8	101.6	101.5	101.9	100.8	101.5
808	2	101.8	101.6	102.4	102.7	102.2	101.8	102.0	102.4	102.3	101.8	102.3	102.0	102.4	102.3	102.4
812	2	101.2	101.2	102.0	101.5	102.7	101.9	101.8	102.0	101.7	101.5	*	101.2	101.8	101.4	102.3
815	2	101.1	101.8	101.3	102.0	102.0	101.7	101.7	101.4	101.7	101.6	101.8	101.8	101.5	101.8	101.3
817	2	100.9	101.8	101.6	101.8	101.4	101.4	101.5	101.1	101.5	101.5	102.4	101.5	102.0	101.5	101.8
818	2	102.0	101.4	101.2	101.7	101.8	101.8	102.2	101.6	101.8	101.7	101.8	101.6	101.8	101.6	101.6
823	2	100.9	101.7	101.2	104.0	102.8	102.4	101.8	101.5	101.4	101.1	101.7	101.5	102.4	102.2	101.5
824	2	101.5	102.1	101.6	102.2	101.8	101.8	102.2	101.8	102.1	101.6	102.3	101.4	101.8	101.6	101.3
826	2	102.1	101.6	102.1	102.2	102.3	101.9	102.9	101.7	101.9	102.2	101.8	102.1	102.8	101.8	102.1
830	2	100.3	101.5	101.6	102.0	102.4	100.9	102.8	100.8	101.1	101.0	101.9	101.2	101.3	100.8	101.2
831	2	101.3	101.1	101.4	102.7	103.6	103.0	101.4	101.4	101.3	101.0	101.9	101.1	101.8	101.5	101.3

Temperatures 103.3°F or greater highlighted

*missed observation

DOC= Day of Challenge

Treatment Group 1 = T01: Controls

Treatment Group 2 = T02: Vaccinates

Table 3: Individual Animal Temperature Data Cont.

		55	56	57	58	59	60	61	62	63	64	65	66	67	68	69	70
802	1	101.8	102.1	101.4	101.6	101.6	101.3	101.8	101.8	101.8	102.0	101.5	102.0	102.0	101.4	101.9	102.0
807	1	102.1	101.5	101.9	101.6	102.0	101.8	101.9	101.5	101.6	101.4	101.7	101.6	101.5	101.7	101.5	101.3
809	1	101.3	101.9	101.0	101.3	101.4	101.4	101.3	101.5	101.7	101.0	100.8	101.4	101.8	101.0	101.4	101.8
810	1	101.2	101.4	101.9	101.4	101.7	101.2	100.8	101.2	101.2	101.2	101.9	101.2	101.0	101.1	101.3	101.5
811	1	101.8	102.3	101.3	101.4	101.3	101.2	102.2	101.1	101.4	101.3	100.7	102.1	101.9	101.2	101.4	101.2
813	1	101.7	101.8	101.1	101.6	101.3	101.4	101.3	101.6	101.9	101.0	101.4	101.7	101.5	101.3	101.6	101.8
814	1	101.5	101.5	101.4	101.3	101.3	101.3	101.3	101.8	101.4	101.7	101.1	101.3	102.0	101.2	101.2	101.4
816	1	101.4	101.2	101.4	101.1	101.7	100.9	101.2	101.5	101.5	101.3	101.1	101.8	101.2	101.3	101.1	101.5
819	1	101.0	101.8	101.1	100.8	101.2	101.3	101.0	101.7	101.0	101.3	100.6	101.2	101.7	101.0	101.3	100.8
820	1	101.8	101.5	101.5	101.7	101.3	101.3	101.6	101.9	102.0	101.7	101.9	101.9	101.9	101.4	101.4	101.7
821	1	101.1	102.1	101.2	102.0	101.4	101.4	101.3	101.6	101.5	101.1	101.5	101.4	101.4	100.8	100.8	101.3
822	1	101.0	101.3	100.7	101.2	101.0	100.8	101.3	101.2	101.7	101.0	101.2	101.3	101.0	101.2	101.2	101.3
825	1	101.4	101.2	100.9	101.4	101.0	101.8	101.4	101.8	101.2	101.4	101.0	101.5	101.3	101.3	101.0	101.7
827	1	102.0	102.2	101.7	102.3	101.4	101.4	102.0	102.0	101.8	101.8	101.4	101.5	101.9	102.0	101.3	101.9
828	1	101.9	101.5	101.1	101.6	101.4	101.3	101.5	100.9	101.0	102.0	101.1	101.7	101.3	101.0	101.5	101.4
801	2	101.7	102.0	101.8	101.5	102.0	101.4	101.2	101.7	101.4	101.4	101.7	101.5	101.6	101.9	101.4	101.6
803	2	101.5	101.5	101.0	101.7	101.1	101.8	101.4	100.9	101.2	101.2	100.8	101.2	101.6	101.3	101.8	101.4
804	2	101.5	101.2	101.5	101.3	101.3	101.7	101.0	101.7	101.3	100.9	101.1	101.4	101.7	101.3	101.3	101.4
805	2	102.0	102.2	101.3	101.5	101.4	101.1	101.9	101.9	101.5	101.8	101.5	101.4	101.4	101.7	101.7	101.5
806	2	101.4	101.7	100.9	101.8	101.0	101.5	101.2	100.8	102.1	100.9	100.6	100.8	100.8	101.4	101.3	101.2
808	2	102.7	102.4	103.0	102.6	102.7	102.4	102.3	102.4	102.4	102.3	101.6	102.0	102.2	102.5	102.2	102.4
812	2	101.7	101.6	101.1	101.7	101.3	101.5	101.6	101.7	101.3	101.5	100.9	101.7	101.3	101.8	101.9	101.8
815	2	101.7	101.6	101.1	101.5	101.4	101.4	100.9	101.3	101.7	101.4	100.8	101.5	101.4	101.7	101.6	101.4
817	2	101.4	101.5	101.4	101.1	101.2	101.3	101.4	101.3	101.5	101.7	102.0	101.4	101.8	101.5	101.4	101.3
818	2	101.6	101.8	100.8	101.8	101.0	101.2	101.8	101.6	101.6	101.7	101.4	101.0	101.4	101.4	101.1	101.5
823	2	102.1	102.0	101.6	102.1	101.7	101.9	102.1	102.1	101.9	101.6	101.0	102.1	102.0	101.9	101.9	101.0
824	2	101.4	101.6	101.9	101.6	102.1	101.0	101.6	101.2	101.3	101.5	100.7	101.3	101.2	101.4	101.2	101.2
826	2	101.8	101.7	102.1	101.4	101.9	102.0	101.7	101.5	101.7	102.0	101.6	102.0	101.3	101.4	101.8	101.7
830	2	101.0	101.7	100.5	101.7	101.0	101.3	101.4	101.4	100.8	101.3	100.6	101.2	101.7	101.6	101.3	101.8
831	2	101.6	101.3	101.3	101.3	101.4	101.8	101.8	101.8	101.8	101.4	101.3	101.7	101.5	101.9	101.2	101.4

Temperatures 103.3°F or greater highlighted

DOC= Day of Challenge

Treatment Group 1 = T01: Controls

Treatment Group 2 = T02: Vaccinates

Table 4: Culture Isolation from Urine of Horses Challenged with *L.pomona*

Animal	Group	41	45	49	52	56	63	70
819	1	NEG						
820	1	NEG	NEG	NEG	NEG	POS	POS	POS
821	1	NEG	NEG	NEG	POS	POS	NEG	NEG
822	1	NEG	NEG	NEG	NEG	POS	NEG	POS
825	1	NEG	NEG	NEG	NEG	POS	NEG	NEG
827	1	NEG	NEG	NEG	NEG	POS	NEG	NEG
828	1	NEG	NEG	POS	POS	POS	POS	POS
802	1	NEG	NEG	NEG	NEG	NEG	POS	NEG
807	1	NEG	NEG	NEG	NEG	POS	POS	NEG
809	1	NEG	NEG	POS	NEG	POS	NEG	NEG
810	1	NEG	NEG	NEG	NEG	POS	NEG	NEG
811	1	NEG	NEG	NEG	POS	POS	POS	NEG
813	1	NEG	NEG	NEG	NEG	POS	NEG	NEG
814	1	NEG	NEG	NEG	NEG	POS	POS	NEG
816	1	NEG	NEG	NEG	NEG	POS	NEG	NEG
801	2	NEG						
817	2	NEG						
818	2	NEG						
823	2	NEG						
824	2	NEG						
826	2	NEG						
830	2	NEG						
831	2	NEG						
803	2	NEG						
804	2	NEG						
805	2	NEG						
806	2	NEG						
808	2	NEG						
812	2	NEG						
815	2	NEG						

Indicates positive isolation

Horses challenged on Day 42

Treatment Group 1 = T01: Controls

Treatment Group 2 = T02: Vaccinates

Table 5: Culture Isolation from Tissues of Horses Challenged with *L. pomona*

Animal		Group	Liver	Kidney
819		1	NEG	NEG
820		1	NEG	POS
821		1	NEG	NEG
822		1	NEG	NEG
825		1	NEG	NEG
827		1	NEG	NEG
828		1	NEG	POS
802		1	NEG	NEG
807		1	NEG	NEG
809		1	NEG	NEG
810		1	NEG	NEG
811		1	NEG	POS
813		1	NEG	NEG
814		1	NEG	NEG
816		1	NEG	NEG
801		2	NEG	NEG
817		2	NEG	NEG
818		2	NEG	NEG
823		2	NEG	NEG
824		2	NEG	NEG
826		2	NEG	NEG
830		2	NEG	NEG
831		2	NEG	NEG
803		2	NEG	NEG
804		2	NEG	NEG
805		2	NEG	NEG
806		2	NEG	NEG
808		2	NEG	NEG
812		2	NEG	NEG
815		2	NEG	NEG

Indicates positive isolation

Treatment Group 1 = T01: Controls

Treatment Group 2 = T02: Vaccinates

Study Type	Safety																																	
Pertaining to	ALL																																	
Study Purpose	Demonstrate safety of product in horses in typical field conditions.																																	
Product Administration	Two doses, administered intramuscularly, 3-4 weeks apart.																																	
Study Animals	Study involved 681 horses at five different geographical sites. Ages ranged from 2 months to 33 years; 207 foals \leq 3 months of age and 474 horses \geq 4 months of age. Horses were assigned to one of two groups (T01 - 340 animals; T02 - 341 animals).																																	
Challenge Description	N/A																																	
Interval observed after challenge	Animals were observed for 20-30 minutes post vaccination, and once daily from day 1 through the end of the study (21 days post-second vaccination) for general health observations and abnormal health events.																																	
Results	<p><u>Study Completion:</u> There were no immediate post-vaccination reactions observed in the vaccinated groups, with 676/681 horses completing the study. The five animals that did not complete the study were due to reasons unrelated to the vaccine.</p> <p>Injection site reactions resolved within 12 days.</p> <p><u>Table 1: Abnormal Health Events with horses administered the product (T01 and T02)</u></p> <table border="1"> <thead> <tr> <th>Treatment / Number of Vaccinations</th> <th>Abnormal Health Event</th> <th>Number/Total (%)</th> </tr> </thead> <tbody> <tr> <td rowspan="7">T01 678 Vaccinations</td> <td>Cough</td> <td>6/678 (0.88%)</td> </tr> <tr> <td>Decreased Appetite</td> <td>2/678 (0.29%)</td> </tr> <tr> <td>Fever</td> <td>3/678 (0.44%)</td> </tr> <tr> <td>Injection Site Swelling (>5.0 cm)</td> <td>1/678 (0.15%)</td> </tr> <tr> <td>Lameness</td> <td>2/678 (0.29%)</td> </tr> <tr> <td>Loss of Condition</td> <td>2/678 (0.29%)</td> </tr> <tr> <td>Nasal Discharge</td> <td>7/678 (1.03%)</td> </tr> <tr> <td>Skin Lesion NOS*</td> <td>2/678 (0.29%)</td> </tr> <tr> <td rowspan="6">T02 680 Vaccinations</td> <td>Abdominal Pain</td> <td>1/680 (0.15%)</td> </tr> <tr> <td>Conjunctivitis</td> <td>1/680 (0.15%)</td> </tr> <tr> <td>Cough</td> <td>7/680 (1.03%)</td> </tr> <tr> <td>Death</td> <td>1/680 (0.15%)</td> </tr> <tr> <td>Fever</td> <td>4/680 (0.59%)</td> </tr> <tr> <td>Injection Site Abscess</td> <td>1/680 (0.15%)</td> </tr> </tbody> </table>	Treatment / Number of Vaccinations	Abnormal Health Event	Number/Total (%)	T01 678 Vaccinations	Cough	6/678 (0.88%)	Decreased Appetite	2/678 (0.29%)	Fever	3/678 (0.44%)	Injection Site Swelling (>5.0 cm)	1/678 (0.15%)	Lameness	2/678 (0.29%)	Loss of Condition	2/678 (0.29%)	Nasal Discharge	7/678 (1.03%)	Skin Lesion NOS*	2/678 (0.29%)	T02 680 Vaccinations	Abdominal Pain	1/680 (0.15%)	Conjunctivitis	1/680 (0.15%)	Cough	7/680 (1.03%)	Death	1/680 (0.15%)	Fever	4/680 (0.59%)	Injection Site Abscess	1/680 (0.15%)
Treatment / Number of Vaccinations	Abnormal Health Event	Number/Total (%)																																
T01 678 Vaccinations	Cough	6/678 (0.88%)																																
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	Conjunctivitis	1/680 (0.15%)																																
	Cough	7/680 (1.03%)																																
	Death	1/680 (0.15%)																																
	Fever	4/680 (0.59%)																																
	Injection Site Abscess	1/680 (0.15%)																																

	Injection Site Alopecia	1/680 (0.15%)
	Injection Site Swelling (>5.0 cm)	1/680 (0.15%)
	Injection Site Swelling (1.5 - 5.0 cm)	1/680 (0.15%)
	Lameness	3/680 (0.44%)
	Loss of Condition	1/680 (0.15%)
	Nasal Discharge	7/680 (1.03%)
	Ocular Discharge	1/680 (0.15%)
	Oedema	1/680 (0.15%)
	Skin Lesion NOS	1/680 (0.15%)
*NOS – Not Otherwise Specified		
USDA Approval Date	6 February 2015	

Study Type	Safety																							
Pertaining to	ALL																							
Study Purpose	Demonstrate safety of product in pregnant horses within the 1 st and 3 rd trimester in typical field conditions.																							
Product Administration	Two doses, administered intramuscularly, 3-4 weeks apart.																							
Study Animals	Study involved 348 pregnant horses, 161 in their 1 st trimester and 187 in their 3 rd trimester, at three different geographical sites. Horses were randomly assigned to either a control group (116 animals: 54 in 1 st trimester and 62 in 3 rd trimester) or a vaccinate group (232 animals: 107 in 1 st trimester and 125 in 3 rd trimester).																							
Challenge Description	N/A																							
Interval observed after challenge	Animals were observed daily for 21 days post-vaccination for any abnormal health events. Animals were evaluated for pregnancy status 21 days following the second vaccination.																							
Results	<p><u>Study Completion:</u> All mares were confirmed to be pregnant prior to vaccination. There were no immediate post-vaccination reactions observed in the vaccinated groups, with 348/348 horses completing the study.</p> <p><u>Table 1: Abnormal Health Events</u></p> <table border="1"> <thead> <tr> <th>Treatment Group</th> <th>Trimester</th> <th>Abnormal Health Event</th> <th>Number/Total (%)[*]</th> </tr> </thead> <tbody> <tr> <td rowspan="3">Control</td> <td>1st trimester</td> <td rowspan="2">Abortions</td> <td>2/108 (1.9%)</td> </tr> <tr> <td>3rd trimester</td> <td>1/124 (0.8%)</td> </tr> <tr> <td>1st trimester</td> <td>Acute Mastitis</td> <td>1/108 (0.9%)</td> </tr> <tr> <td rowspan="3">Vaccinate^{**}</td> <td>3rd trimester</td> <td>Lameness</td> <td>1/250 (0.4%)</td> </tr> <tr> <td>1st trimester</td> <td>Skin Oedema</td> <td>1/214 (0.5%)</td> </tr> <tr> <td>1st trimester</td> <td>Acute Mastitis</td> <td>1/214 (0.5%)</td> </tr> </tbody> </table> <p>[*]Total number of injections from both vaccinations. ^{**}Two mares in the vaccinate group delivered one healthy foal each.</p>	Treatment Group	Trimester	Abnormal Health Event	Number/Total (%) [*]	Control	1 st trimester	Abortions	2/108 (1.9%)	3 rd trimester	1/124 (0.8%)	1 st trimester	Acute Mastitis	1/108 (0.9%)	Vaccinate ^{**}	3 rd trimester	Lameness	1/250 (0.4%)	1 st trimester	Skin Oedema	1/214 (0.5%)	1 st trimester	Acute Mastitis	1/214 (0.5%)
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USDA Approval Date	28 July 2016																							

Study Type	Safety														
Pertaining to	ALL														
Study Purpose	Demonstrate safety of product in pregnant horses within their 2 nd trimester in typical field conditions.														
Product Administration	Two doses, administered intramuscularly, 3-4 weeks apart.														
Study Animals	Study involved 299 horses in their 2 nd trimester of pregnancy at three different geographical sites. Horses were randomly assigned to either a control group (102 animals) or a vaccinate group (207 animals).														
Challenge Description	N/A														
Interval observed after challenge	Animals were observed daily for 21 days post-vaccination for any abnormal health events. Animals were evaluated for pregnancy status 21 days following the second vaccination.														
Results	<p><u>Study Completion:</u> All mares were confirmed to be pregnant prior to vaccination. There were no immediate post-vaccination reactions observed in the vaccinated groups, with 299/309 horses completing the study. The ten animals that did not complete the study were due to reasons unrelated to the vaccine.</p> <p>There were no abnormal health events in the control group during the study.</p> <p><u>Abnormal Health Events in Vaccinates:</u></p> <table border="1"> <thead> <tr> <th>Abnormal Health Event</th> <th>Number/Total (%)*</th> </tr> </thead> <tbody> <tr> <td>Abdominal Pain**</td> <td>1/397 (0.25%)</td> </tr> <tr> <td>Abortion***</td> <td>2/397 (0.50%)</td> </tr> <tr> <td>Conjunctivitis</td> <td>2/397 (0.50%)</td> </tr> <tr> <td>Muscle Pain</td> <td>1/397 (0.25%)</td> </tr> <tr> <td>Ocular Discharge</td> <td>1/397 (0.25%)</td> </tr> <tr> <td>Skin Lesion NOS****</td> <td>2/397 (0.50%)</td> </tr> </tbody> </table> <p>*Total number of injections from both vaccinations **Affirmed by licensee not to be caused by vaccination ***Two mares had abortions and these were not related to vaccine administration as affirmed by licensee. ****Not otherwise specified.</p>	Abnormal Health Event	Number/Total (%)*	Abdominal Pain**	1/397 (0.25%)	Abortion***	2/397 (0.50%)	Conjunctivitis	2/397 (0.50%)	Muscle Pain	1/397 (0.25%)	Ocular Discharge	1/397 (0.25%)	Skin Lesion NOS****	2/397 (0.50%)
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